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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Michael R Ward
MORRISON & FOERSTER LLP
425 MARKET STREET
San Francisco, CA 94105-2482

EXAMINER

WELLS, LAUREN Q.

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 04/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/657,276

Examin r

Lauren Q Wells

Applicant(s)

BRIDON ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-9,11-17 and 21-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-9,11-17 and 21-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 6, 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claims 1-5, 7-9, 11-17 and 21-25 are pending. The Amendment received March 5, 2002, cancelled claims 6, 10 and 18-20, and amended claims 7-9, 11-12, 15-17, and 21-23.

Election/Restrictions

Applicant's election with traverse of the Restriction/Election Requirement in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the claims are directed a platform technology that is applicable to any peptide in need of stabilization in vivo against peptidase activity. This is not found persuasive, as it would be impossible to search all peptides and all peptidases associated with the instant claims, thereby placing a serious burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7-9, 11-17 and 21-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for protein sequences in Examples 1-70 of the specification, does not reasonably provide enablement for all peptides composed of between 3 and 50 amino acids that are stabilized against any/all peptidases. The specification does not

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enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation wherein patients susceptible to having symptoms of a disorder or dysfunction are treated with the claimed invention.

The disclosure of the present invention is drawn to modified therapeutic peptides capable of forming a peptidase stabilized therapeutic peptide composed of between 3 and 50 amino acids comprising a therapeutically active region, a less therapeutically active region, and a reactive group. While the skilled artisan would be motivated to modify proteins of Examples 1-70, the artisan would not know what other proteins or peptidases Applicant is referring to which would be compatible with the instant invention. Hence, a skilled artisan in the art would not be able to readily ascertain the unlimited number of proteins composed of between 3 and 50 amino acids and the unlimited number of peptidases that the proteins are stabilized against. Thus, the skilled artisan would be forced to randomly test various proteins in combination with various peptidases to determine which proteins can be modified to form a protein stabilized from a peptidase.

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Furthermore, the amount of guidance present in the specification fails to present the necessary instruction to determine what proteins stabilized from peptidase activity are encompassed by the claims.

The specification does not provide guidance for all proteins between 3 and 50 amino acids in combination with all peptidases that are stable. Though a few working examples are given, they do not come near to exemplifying all peptides composed of between 3 and 50 amino acids or all peptidases that are defunct of acting on the modified peptides. Without such information, one skilled in the art could not predict which peptides of between 3 and 50 amino acids and peptidases out of the vast number of known and hypothetical peptides of between 3 and 50 amino acids and peptidases are encompassed by Applicant's phrase "a modified therapeutic peptide capable of forming a peptidase stabilized therapeutic peptide composed of between 3 and 50 amino acids". Therefore, due to the lack of guidance and the amount of experimentation required to identify which peptides are stabilized in the presence of which peptidases, the therapeutic peptides are not properly enabled by the instant specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 7-9, 11-17 and 21-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) Claims 1-5, 7-9, 11-17 and 21-25 are rejected because the peptide in these claims is not defined with any chemical or physical characteristic, but only by functional properties. A claim to a material defined solely in terms of what it can do, or a property thereof, does not

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particularly point out the claimed invention. Thus, the scope is indefinite. See *ex parte Pulvari* (POBA 1966) 157 USPQ 169.

(ii) The term “capable of” in claims 1 (line 1), 7 (lines 9-10), 16 (line 10) is vague and indefinite. It has been held that the recitation that an element is “capable of” performing a function is not a positive limitation but only requires the ability to so perform that function. It does not constitute a limitation in any patentable sense. In *re Hutchison*, 69 USPQ 138.

(iii) The term “stabilized” in claims 1 (lines 2, 9) is vague and indefinite, as it is not clear what stabilized means. Does it mean that the peptide is never cleaved by a peptidase? Does it mean that the peptide has a 51% chance of not being cleaved by a peptidase? What does it mean?

(iv) The terms “therapeutically active region” and “less therapeutically active region” in claim 1 (lines 4-5), 2 (line 1), 3 (line 1), 4 (line 1), 5 (line 1), 16 (lines 3, 4) are vague and indefinite. These terms are not defined in the specification and one of ordinary skill in the art would not be apprised of them. What defines an area that is therapeutically active versus one that is not? How is one area less active than other?

(v) The term “stable” in claim 1 (line 8) is a relative term which renders the claim indefinite. The term “stable” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

(vi) The term “succinimidyl and maleimido groups” in claim 1 (line 11) is vague and indefinite, as it is not clear what compounds are encompassed by the term “groups”. The

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specification does not define this term and one of ordinary skill would not be apprised of all succinimidyl and maleimido compounds encompassed by the term “groups”.

(vii) The term “amino acid amino acid” in claim 7 (line 4) is vague and indefinite, as it is not clear if this is a typo or if something else is being referred to.

(viii) The term “reactive functionality on a blood component” in claims 7 (line 10), 16 (part c) is vague and indefinite, as it is not clear what this refers to. Regarding the reactive functionality, is this a compound? Is this a protein? Is this a DNA molecule? Regarding the blood component, is this a hormone? Is this a cell? Is this a blood vessel? What do these terms refer to? The specification does not adequately define this term and one of ordinary skill in the art would not be apprised of it.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-9, 11-17 and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pouletty et al. WO 95/10302 in view of Oppenheim et al. (5,837,247).

Pouletty et al. teach a composition comprising a first conjugate for use in a method for the extended presence of a target binding member in the blood stream of a mammalian host. The target binding member binds to a target which is a physiologically active agent which may be

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present in the blood stream of the host. Administered to a host is a first conjugated comprising an anchor and a first member of a specific binding pair. The first member of the binding pair is a member of a linking specific binding pair, wherein the reciprocal member is conjugated to the target binding member to form a second conjugate. The anchor binds specifically to a long-lived blood associated protein or is a reactive functionality which covalently bonds to a long-lived blood associated protein. Serum albumin is disclosed as a long-lived blood associated protein. The anchor is disclosed as comprising N-hydroxy succinimide ester. The conjugate may be administered in vivo or ex vivo. Disclosed is a method of analyzing the peptide-blood component. The target binding member may provide for a wide variety of functions. The reference lacks specific teachings on amino acid length and SEQ ID NO: 1032.

Oppenheim et al. teach chemoactive agents for T-cells. Disclosed as a chemoactive agent is a defensin protein of SEQ ID NO: 1032 for inducing or stimulating T-cell chemotaxis in a mammalian subject.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute SEQ ID NO: 1032 of Oppenheim et al. for the second conjugate protein of Pouletty et al. because a) Pouletty et al. teach their invention for extending the in vivo lifetimes of physiologically active agents and SEQ ID NO: 1032 is a physiologically active agent; b) Pouletty et al. teach malignant cells as targets for their therapeutic conjugates and SEQ ID NO: 1032 targets malignant cells.

Unexpected Results

It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated

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with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, the data on pages 92-181 of the specification have been considered but not found persuasive because the data merely demonstrate the effectiveness of the instant peptide against peptidases. This is seen to be an expected result based on the cited prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on T-F (6-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
April 23, 2002

RUSSEL TRAVERS
PRIMARY EXAMINER
GROUP 1200